



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
|--------------------|-------------|-----------------------|---------------------|
| 09/366,133         | 08/02/99    | PELLEYMOUNTER         | M A-345C            |

US PATENT OPERATION/ JDE  
DEPT 430 M/S 27-4-A  
AMGEN INC.  
ONE AMGEN CENTER DRIVE  
THOUSAND OAKS CA 91320-1799

HM22/1107

EXAMINER

DRAPER, G  
ART UNIT PAPER NUMBER

1647  
DATE MAILED: 11/07/00

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-12 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claims 1-12 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1647

**Part III: Detailed Office Action**

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1647, Group 1640, Technology Center 1600.
2. A telephone call was made to Karol Pessin on 11-6-00 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicants expressly requested a written restriction requirement.

**3. Restriction Requirement:**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a method of treating excess weight, classified in classes 424 and 514, subclasses 85.2 and 2+ respectively.
- II. Claims 5-10, drawn to DNA encoding the Ob protein and vectors, classified in classes 536 and 435, subclasses 23.5 and 320.1 respectively.
- III. Claims 11-12, drawn to a method of refolding a partially purified Ob protein, classified in class 530, subclass 351+.

The inventions are distinct, each from the other because:

Inventions Group II and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the DNA of Group II can be used other than to make the Ob protein such as its use in therapy or diagnostically. Furthermore, the protein can be made other than with the refolding method of Group III, such as its preparation from nature using various isolation/purification/chromatographic processes; or it could be made by chemical synthesis.

It is further pointed out that inventions of Group I and III are directed to two different and distinct methods. Although there are no provisions under the section for "Relationship of

Art Unit: 1647

inventions" in MPEP 806.05 for different/distinct processes /methods, restriction is deemed to be proper because these processes/methods appear to constitute patentably distinct inventions. These two methods require the use of physically and functionally distinct elements, different components and steps, as well as have different starting features and different final outcomes, which are not required one for the other. The method of refolding the ob protein is quite distinct from a method of using the ob protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, which are not co-extensive, and because of the recognized divergent subject matter between the receptor and the methods of making and using the antibodies; there are different issues for the search and examination of each group; and in view of the grouping of multiple elements in Group I to satisfy the 371 practice, to search additional groups would be an undue burden on the Examiner, therefore, restriction for examination purposes as indicated is proper.

4. **Advisory Information:**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1647, whose telephone number is (703) 308-4232**. Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Art Unit: 1647

**Official papers filed by fax should be directed to (703) 308-4242.** Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.



GARNETTE D. DRAPER  
PRIMARY EXAMINER  
GROUP 1800